Draft PBT Rule Outline

Part I - General Provisions

WAC 173-XXX- 010 Purpose and Goals

(1) What is the purpose of this chapter? The purpose of this chapter is to establish processes that Ecology will use to minimize threats to human health and the environment caused by the use and release of persistent bioaccumulative toxins. The chapter:[1]

(a) Establishes criteria Ecology will use to identify persistent bioaccumulative toxins;

(b) Establishes a list of persistent bioaccumulative toxins and procedures Ecology will use to review and periodically update the list;

(c) Establishes criteria for selecting persistent bioaccumulative toxins for which Ecology will prepare chemical action plans; and

(d) Defines the scope and content of chemical action plans and establishes processes Ecology will use to prepare those plans.

(2) **What are the goals of this chapter?**[2]

Alternative A: The goal of this chapter is to "reduce, and where possible, eliminate"[3] threats to human health and the environment posed by the use and release of persistent bioaccumulative toxins.

Alternative B: The goal of this chapter is to "manage"[4] threats to human health and the environment posed by the use and release of persistent bioaccumulative toxins.

Alternative C: The goal of this chapter is to "minimize and, where possible, eliminate"[5] threats to human health and the environment posed by the use and release of persistent bioaccumulative toxins.

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[1] Subsections (a) – (c) address the three rulemaking purposes identified by the Legislature in the 2004 budget proviso. Specifically, the Legislature directed Ecology to (1) develop specific criteria by which chemicals may be included on a PBT list, (2) develop a specific list of PBTs and (3) establish criteria for selecting chemicals for chemical action plans. The fourth rulemaking purpose is designed to respond to the suggestions from the Advisory Committee on the question of what makes a good rule (August 18th meeting). Specifically, several members that it was important to provide some level of certainty and predictability on how Ecology will address chemicals that are included on the PBT list. .

[2] Four different goal statements are included here to reflect the differing views Ecology heard at the September 8 PBT Rule Advisory Committee meeting. Ecology is expecting further feedback on this issue at the Oct. 14 PBT Rule Advisory Committee meeting. For the purposes of this draft of the PBT rule, we used the language found in Alternative A.

[3] This draft alternative is based on the vision and goal statements in the proposed Ecology PBT Strategy released by Ecology in December 2000.

[4] This draft alternative is based on suggestions provided by several advisory committee members at the Sept. 8 PBT Rule Advisory Committee meeting. The members suggesting this approach expressed the opinion that the use of the word "manage" captures the concept that a wide range of measures may be used to address PBT uses and releases and that a broad term is consistent with international agreements that consider elimination, restrictions and use of best available technology.

Alternative D: The goal of this chapter is to reduce threats to human health and the environment through actions to manage, minimize and, where feasible, eliminate uses and releases of persistent bioaccumulative toxins.[6]

WAC 173-XXX-015 Applicability[7]

(1) This chapter applies to the department of Ecology. Nothing herein shall be construed to diminish Ecology's authority to address a permitted or unpermitted release or threatened release of any PBT under other applicable laws and regulations.

(2) This chapter provides opportunities for the public to participate in the Ecology processes for identifying PBTs and developing recommendations on measures to address current uses and releases, contamination problems resulting from past releases and proposed uses or releases from new sources. The chapter does not impose new requirements on persons who use or release PBTs, have caused past releases of PBTs or propose new uses or releases.

WAC 173-XXX-020 Chapter Summary

(1) **Introduction**. This section provides a summary of the PBT Rule. If there are any inconsistencies between this section and any specifically referenced sections, the referenced section will govern.

(2) **What are persistent bioaccumulative toxins (PBTs)?**[8] PBTs are chemicals that:

- Remain in the environment for a long time (persist) without breaking down;
- Accumulate in the environment and build up in the tissues of humans, fish and animals (bioaccumulate); and
- Are toxic to living organisms, including humans.

(3) Identifying and listing PBTs. This chapter will contain a list of PBTs that require further actions to reduce or where possible eliminate uses and releases in Washington.

(a) **PBTs list**. The current list of persistent bioaccumulative toxins is specified in WAC 173-XXX-110.

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[5] This draft alternative is based on suggestions provided by some advisory committee members at the September 8 meeting that the word "reduce" is too vague and that use of terms like "minimize" would help to capture a goal of reducing causes and releases to the smallest possible amount.

[6] This draft alternative attempts to integrate key concepts embedded in the other three alternatives: (1) the environmental goal (reduce and, where possible, eliminate uses and releases); (2) management options for achieving the goal (the "means" or "mechanisms" to achieve an "end"); and (3) feasibility will influence the availability of management options.

[7] Ecology has not decided whether it is necessary to include an applicability section in this rule given the rule is procedural in nature and participation by members of the public is voluntary. However, given the discussions at the first two Advisory Committee meetings, the Department decided to include a draft applicability section. The draft section is designed to clarify two points: (1) the rule is procedural and establishes criteria and procedures that are applicable to Ecology; and (2) the rule does not create new requirements for persons who use or release PBT chemicals. .

[8] This general definition is found in the Ecology PBT Strategy (December 2000).

(b) **Criteria for identifying and adding PBTs to the list.** . Ecology will use the PBT criteria specified in WAC 173-XXX-120 to determine whether a chemical, or group of chemicals, should be included on the PBT list.

(c) **Criteria for removing PBTs from the list.** Ecology will use the criteria in WAC 173-XXX-130 to determine whether a chemical, or group of chemicals, should be removed from the PBT list.

(d) **Process for adding and removing PBTs from the List**. WAC 173-XXX-140 describes the process that Ecology will use to add and remove chemicals from the PBT List.

(d) **Involving the public in updates of the PBT list.** If Ecology decides to revise the PBT list it will use the procedures specified in WAC 173-XXX-150 to notify and involve the public.

(e) **Amending the PBT list.** Ecology will make amendments to this chapter using the process described in Chapter 34.05 RCW, The Administrative Procedure Act.

(4) Priorities for chemical action plans or CAPs. Ecology will prepare chemical action plans (CAPs) for the chemicals included on the PBT list. Ecology will use the evaluation criteria[9] specified in WAC 173-XXX-210 to select and prioritize chemicals for which Ecology will prepare CAPs.

(5) **Chemical action plans or CAPs**. When preparing a CAP, Ecology will include recommendations on actions to reduce, and where possible eliminate, *(include goal language here when decided)*[10] the use and release of specific PBTs. The process for preparing chemical action plans includes the following steps[11]:

(a) **Information collection**. Ecology will develop and implement a plan for collecting the data and information needed to support evaluations and decisions on actions to minimize uses and releases of PBTs in Washington. This includes, but is not limited to:

- Information on products and uses,
- Environmental releases,
- Environmental concentrations, substitutes,
- Technical options for managing uses and releases,
- Costs of alternate management options,
- Other information Ecology determines is necessary to support the decision-making process.

(b) **Uses and releases**. Ecology will identify uses and sources of the PBTs addressed in the plan. Ecology will prepare estimates on the amount of each PBT released into the Washington environment.

(c) **Management alternatives**. Ecology will identify alternative approaches for reducing, and where possible eliminating, the use and release of each PBT.

[9] To be further discussed at the Sept. 29 PBT Rule Advisory Committee meeting.
[10] This language could change to reflect which goal Ecology decides upon for Section 010 (2).
[11] This is from the Ecology PBT Strategy (December 2000) and from Ecology's track record in doing the Mercury Chemical Action Plan and current development of the PBDE Chemical Action Plan.

(d) **Technical feasibility**: Ecology will evaluate the technical feasibility of implementing the management alternatives.

(e) **Economics.** Ecology will evaluate the costs of implementing the management alternatives.

(f) **Regulatory and non-regulatory analysis**. Ecology will evaluate regulatory and non-regulatory approaches that influence current uses, releases and *management* of each PBT.

(g) **Recommendations**. Ecology will prepare a draft CAP for public review and comment that provides recommendations on actions for reducing, and where possible eliminating, the uses and releases of each PBT.

(h) **Finalizing the CAP.** After public comment on the draft CAP, Ecology will prepare a final chemical action plan.

WAC 173-XXX-035 Exemptions to the PBT list

Any pesticide with a valid registration on or after the effective date of this rule issued by the environmental protection agency under the federal insecticide fungicide and rodenticide act, 7 U.S.C. 136 et seq., or any fertilizer regulated under the Washington fertilizer act, chapter 15.54 RCW, shall not be included in a persistent bioaccumulative toxin rulemaking process, list, or chemical action plan undertaken by the department of ecology[12].

WAC 173-XXX-040 Administrative Principles[13]

(1) **Introduction**. Ecology will implement this rule consistent with the administrative principles described in this section.

(2) **Sound scientific foundation**. Ecology believes that decisions on PBTs and actions for reducing, or when possible eliminating, their use and release should be based on sound scientific information.

(3) **Public involvement**. Ecology will encourage public involvement during decision-making processes for identifying PBTs and preparing recommendations on actions for reducing and, where possible, eliminating their use and release.

(4) **Clear documentation**. Ecology intends to provide clear and understandable descriptions and rationale for decisions implementing this chapter.

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[12] The pesticide exemption language comes from the 2004 budget legislation language.

[13] Members of the advisory committee have expressed several concerns about "how" Ecology will implement a rule (independent of "what" criteria and processes are identified in the rule). Similar concerns have been raised in other rulemaking processes and at least one rule (the MTCA Cleanup Regulation) includes an Administrative Principles section that is designed to provide some direction on how that rule will be implemented. Ecology has used that rule as a model to create a similar draft section for this chapter. The six implementation "principles" included in the draft section are based on discussions and suggestions provided by the advisory committee during the August 18 meeting (#1) during the discussion topic "What makes a good rule?" Ecology is interested in obtaining feedback from the advisory committee on (1) Does the committee believes this type of section is useful to include in the PBT rule?; (2) do the draft "principles" capture the important concepts identified at the August meeting; and (3) Are there other implementation principles that the advisory committee believes should be included in this section?

(5) **Predictability**. Ecology believes it is important that this chapter be implemented in ways that allow stakeholders to plan their participation in decision-making processes and future responses to recommendations that result from those processes.

(6) **Coordination.** When appropriate, Ecology will coordinate with other state agencies and local governments, tribes, and interested parties in the development and implementation of CAPs and when revising the PBT List.

WAC 173-XXX-050 Definitions[14]

"Bioaccumulation" means the process by which organisms accumulate a chemical in their body as a result of uptake from all environmental sources.[15]

"Bioaccumulation factor" or "BAF" means the ratio of the concentration of a chemical in an organism to the concentration of the chemical in the surrounding environment. The BAF is a measure of the extent to which the organism accumulates the chemical as a result of uptake through ingestion as well as contact from contaminated media, such as water.[16]

"Bioconcentration factor" or "BCF" means is the ratio of the concentration of a chemical in an organism to the concentration of the chemical in the surrounding environment. The BCF is a measure of the extent of chemical partitioning between and their surrounding environment. The BCF does not evaluate uptake through ingestion, only through contact with environmental media. [17]

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[14] Ecology has reviewed the meeting notes and summaries from the first two meetings (as well as various PBT strategies, rules, treaties) and identified a preliminary list of terms that we believe should be defined in the rule. All definitions are very draft at this time. Ecology is interested in feedback from the committee on: (1) Does the committee believe that the rule should include definitions for the identified terms?; (2) Does the committee believe the draft definitions are clear and accurate? (if not, does the committee have suggestions for improving the clarity and accuracy?); and (3) Does the committee believe this section should include definitions for other terms?

[15] The draft definition is based on the definition of bioaccumulation in the preamble to the proposed amendments to the Toxic Release Inventory rules (64 FR 703). EPA has adopted similar definitions in other rules and guidance materials. The draft definition incorporates the concept of (1) a process, (2) accumulation in organisms and (3) uptake from multiple sources. An alternate approach would be to use the term "bioaccumulation potential" which is more focused on the properties of the chemical (as opposed to the process). EPA included the following definition for this term in the technical support documents for the WMPT (EPA, 1998) and the Hazardous Waste Identification Rule (EPA, 1995): "Bioaccumulation potential is the capacity of a chemical to increase in concentration or accumulate (be stored in tissue) in an organism as a result of uptake from all environmental sources over a period of time".

[16] The draft definition was taken from the WMPT technical support document (EPA 1998) which references the Hazardous Waste Identification Rule. It is consistent with other standard definitions of the term found in other laws, treaties, guidance materials and textbooks and captures the concepts of (1) ratio of concentrations in tissue and surrounding media; (2) uptake from all environmental media or sources; (3) it is a measure of bioaccumulation or bioaccumulation potential.

[17] The draft definition was taken from the WMPT technical support document (EPA 1998) which references the Hazardous Waste Identification Rule. It is consistent with other standard definitions of the term found in other laws, treaties, guidance materials and textbooks and captures the concepts of (1) ratio of concentrations in tissue and surrounding media; (2) partitioning between organism and environmental media; (3) it is a measure of bioaccumulation or bioaccumulation potential.

"Carcinogen" means any chemical or agent that produces or tends to produce cancer in humans. For implementation of this chapter, the term carcinogen applies to chemicals on the United States Environmental Protection Agency lists of A (known human) and B (probable human) carcinogens, and any chemical that causes a significant increased incidence of benign or malignant tumors in a single, well conducted animal bioassay, consistent with the weight of evidence approach specified in the United States Environmental Protection Agency's Guidelines for Carcinogen Risk Assessment as set forth in 51 FR 33992 et seq.[18]

"Chemicals" means a naturally occurring element, or mixture of organic and inorganic chemicals that is produced by or used in a chemical process.

"Chemical group" means a grouping of chemicals which share a common chemical structure with differing molecular variations.

"Chemical Action Plan" or "CAP" means a plan that identifies, characterizes and addresses uses and releases of a specific PBT or a group of PBTs and facilitates implementation of measures to manage, minimize and, where feasible, eliminate such uses and releases.[19]

"Cross-media Transfer of Chemicals" means the movement of a chemical from one medium, such as air, water, soil, or sediment, to another.

"Ecology" means the department of ecology.

"Environment" means any plant, animal, natural resource, surface water (including underlying sediments), ground water, drinking water supply, land surface (including tidelands and shorelands) or subsurface strata, or ambient air within the state of Washington or under the jurisdiction of the state of Washington.

"Environmental half-life" means the time required for the concentration of a chemical to diminish to half its original value. The environmental half-life of a chemical is a measure of that chemical's persistence in the environment.

"Manage" actions to reduce the uses and releases of PBTs and may include application of best available technology to reduce PBT generation and releases, process changes to reduce or eliminate PBT generation and releases, product substitution to eliminate uses and releases and other measures to directly or indirectly reduce threats to human health and the environment.[20].

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[18] The approach used by Ecology to prepare the PBT working list includes separate toxicity criteria for carcinogenic and non-cancer health effects. The draft definition for "carcinogen" is copied from the MTCA Cleanup Regulation (similar if not identical definitions are found in other Ecology rules and guidance). If the final PBT criteria incorporate the EPA toxicity criteria (or similar approaches), this definition would need to be updated to reflect the current EPA guidance on Carcinogen Risk Assessment.

[19] The draft definition is based on the concepts and language on action plans in the Stockholm Convention on Persistent Organic Pollutants (See Article 5).

[20] The draft definition is designed to capture the concepts discussed at the September 8 Advisory Committee meeting. Specifically, the draft definition reflects suggestions that "manage" is a broad term that captures many options for reducing/eliminating PBT uses and releases. The range of examples are based on the measures identified in the Stockholm Convention on Persistent Organic Pollutants (See Article 5).

"Media or Medium" means a component of the environment (air, water, soil or sediment) in which a contaminant is measured and an organism lives its life, and from which an organism can accumulate contaminants.

"Persistent bioaccumulative toxin" or "PBT" means a chemical or chemical group that meets or exceeds the criteria for persistence, bioaccumulation and toxicity criteria established in this chapter

"**Persistence"** means the tendency of a chemical to remain in the environment without transformation or breakdown into another chemical form. It refers to the length of time a chemical is expected to reside in the environment and be available for exposure.[21]

"Reduce and where possible eliminate" means actions to reduce the uses and releases of PBTs and may include process changes designed to reduce or eliminate PBT generation and releases or product substitution to eliminate uses and releases[22].

"Toxicity" means the ability of a substance to cause injury or death to an organism, including humans[23].

[21] The draft definition was taken from the WMPT technical support document (EPA 1998). It is consistent with other standard definitions of the term found in other laws, treaties, guidance materials and textbooks and captures the concepts of (1) length of time a chemical remains in the environment; (2) available for exposure. A separate definition is provided for "environmental half-life" which is the standard measure of persistence.
[22] The draft definition reflects the term as it is generally applied in the Ecology PBT Strategy (December 2000).
[23] The MTCA Cleanup Regulation (Chapter 173-340 WAC) includes definitions for "acute toxicity" and "chronic toxicity". The draft definition for "toxicity" is based on those two definitions. Alternate definitions could be developed based on the definition of "toxic" found in the Dangerous Waste Regulations (See WAC 173-303-040) which includes the following definition: "Toxic" means having the properties to cause or significantly contribute to death, injury, or illness of man or wildlife.